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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/690,320	10/20/2003	Susan A. Kingsman	674523-2030	4549

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FROMMER LAWRENCE & HAUG  
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NEW YORK, NY 10151

EXAMINER

MONTANARI, DAVID A

ART UNIT PAPER NUMBER

1632

DATE MAILED: 12/12/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

10/690,320

Applicant(s)

KINGSMAN ET AL.

Examiner

David Montanari

Art Unit

1632

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 20 September 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 12-14, 18-24, 29, 31, 32, 34, 38 and 40 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 12-14, 18-24, 29, 31-32, 34, 38, and 40 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

### **DETAILED ACTION**

1. Applicants arguments and amendments filed 9/20/2006 have been entered.
2. A new examiner has taken over prosecution of this case.
3. The rejection of claim 13 under 35 USC 101 is withdrawn.
4. The rejection of claims 13, 18, 19, 22, and 23 under 35 USC 102(b) is withdrawn.
5. The rejection of claims 12-14, 18, 19, 21-24, 32, and 38 under 35 USC 102(e) is withdrawn.
6. The rejection of claims 12, 13, 24, 31, 34, and 40 under 35 USC 103(a) is withdrawn.
7. Claims 12-14, 18-24, 29, 31-32, 34, 38, and 40 are examined in the instant application.

### ***Claim Rejections - 35 USC § 101***

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 12 is rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. Claim 12 is drawn to a target adipose tissue cell transduced with a lentiviral vector. The subject matter encompassed by the claim is indistinguishable from that which occurs in nature when a virus infects an adipose cell, such as when CMV infects adipose tissue {Bruggerman et al. (1987) Intervirology 27:32-7; Abstract; pg. 32, col. 1}. The addition of the word "isolated" before the word target would obviate this rejection.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

Art Unit: 1632

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 12-14, 18-24, and 29 remain rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of transducing a target mammalian adipose tissue cell, with a with lentiviral vector pseudotyped with the VSV-G protein, comprising at least one nucleotide sequence of interest, and said transduced target adipose cell, does not reasonably provide enablement for a method of transducing or infecting an adipose cell with any viral vector to treat any disease associated with adipose tissue metabolism. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims for reasons of record in the office action mailed 6/21/2006.

### *Response to Arguments*

Applicants argue in amendment filed 9/20/2006 that in an effort to advance prosecution, the claims have been amended to address the issues raised in the office action. This is not persuasive. The instantly amended claims do not recite the limitations discussed in the scope of enablement in the previous office action. The claims still encompass any envelope protein with which the lentiviral vector will be pseudotyped with. The earlier office action provides clear evidence that the transduction of adipose cells via any route of lentiviral vector administration is highly unpredictable. For example, the specification fails to disclose that systemic administration

Art Unit: 1632

would result in the transduction of adipose cells to express an NOI. Thus for reasons of record and above the rejection is maintained.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 12-14 and 20-22 are rejected under 35 U.S.C. 102(b) as being anticipated by Dewhurst et al. (2000, *Frontiers in Bioscience*, Vol. 5, pgs. 30-49), and further evidenced by Hazan et al. (2002, *FASEB*, Vol. 16, pgs. 1254-1256).

Claims 12-14 and 20-22 are drawn to a target adipose tissue cell transduced with a lentiviral vector wherein the lentiviral vector is pseudotyped with at least part of an env protein, and a method of transducing a target adipose tissue cell comprising contacting the cell with a lentiviral vector.

Dewhurst et al. teach a comprehensive review of HIV infection. HIV is a lentivirus, which has a pathogenesis of hiding in many cell types when undergoing antiretroviral treatment. Dewhurst et al. continues to teach that HIV can mutate on a massive scale resulting in a wide variety of HIV genomes (pg. 33 col. 1 parag. 1).

Art Unit: 1632

Hazan et al. teach that HIV can infect adipose tissue cells by virtue of adipose cell expressing CD4, CXCR4 and CCR5 receptors (pg. 1254). Hazan continues that adipose cells are susceptible to HIV transduction (pg. 1256 Fig. 2).

Based upon the teachings of Dewhurst and Hazan, it would be an inherent property that the lentivirus HIV produced in vivo is pseudotyped with host cellular proteins and infects adipose tissue in humans that are HIV positive, and thus claims 12-14 and 20-22 read on a product of nature. Thus the cited art provides the requisite teachings and motivation to make and use the claimed invention.

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Montanari whose telephone number is 1-571-272-3108.

The examiner can normally be reached on M-Tr 8-6.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Peter Paras can be reached on 1-571-272-4517. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1632

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

David A. Montanari, Ph.D.



SUMESH KAUSHAL, PH.D.  
PRIMARY EXAMINER